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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/310,791 09/29/94 STACHE

U 02481.1403

KESTLER, K EXAMINER

12M2/0725

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ART UNIT	PAPER NUMBER
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1204

DATE MAILED: 07/25/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 21 April 95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.      | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-5 are pending in the application.  
Of the above, claims 3 are withdrawn from consideration.
2. ☒ Claims 6 has been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-2 and 4-5 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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### **First Action on the Merits**

#### **I. The election of Group I with traverse is acknowledged.**

Applicant's election with traverse of Group 1, claims 1-2 and 4, in Paper No. 5 is acknowledged. The traversal is on the ground(s) that there is no burden on the examiner to search groups I and III together. Upon reconsideration the examiner has combined Groups I and III. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement between groups I and II, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)). Claims 1-2 and 4-5 have been examined. Claim 6 was cancelled, and claim 3 is withdrawn from further consideration as being drawn to a nonelected invention.

#### **II. Claims 1 and 2 are objected to as being duplicates.**

Claim 2 states that all other variables are the same as claim 1 and defines R<sup>2</sup> as a (C<sub>1</sub>-C<sub>8</sub>)-alkyl, a phenyl, or a benzyl group. However, these are the only possibilities for R<sup>2</sup> in claim 1. Therefore, the claims describe the exact same genus of compounds. Upon either claim being found allowable the other will be rejected. See M.P.E.P. § 706.03(k).

#### **III. The claims are rejected under 35 U.S.C. § 102(b).**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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**A. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Villax, et al.**

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Villax, et al.

Villax, et al teach 17,21-dicarboxylic esters having an aromatic group in the acid moiety attached at the 21 position. The reference specifically teaches the following compounds: 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-acetate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-propionate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-butyrate-21-benzoate; and 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-valerate-21-benzoate. (Col 4, lines 23-42) It also teaches that these compounds may be mixed with pharmaceutically acceptable excipients and applied topically to treat corticosteroid-responsive dermatoses. (Col 4, Ins 48-62) These compounds, compositions, and methods taught by the reference are encompassed by the instant claims.

**B. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kamano, et al.**

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kamano, et al.

Kamano, et al teach 17,21-carboxylic esters and specifically teach the following compounds: 17-acetoxy-21-benzoyloxy-11-hydroxy-6-methyl-1,4-pregnadiene-3,20-dione and 21-benzoyloxy-11-hydroxy-6-methyl-17-propionyloxy-1,4-pregnadiene-3,20-dione. (Col 9) The reference also teaches that the compounds can be formulated into compositions useful for the treatment of dermal

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disorders. (Col 8, Ins 17-23 and 42-47) These compounds, compositions and methods are encompassed by the instant claims.

**IV. The claims are rejected under 35 U.S.C. § 103.**

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

**A. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over 1-2 and 4-5.**

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Villax, et al.

Villax, et al teach 17,21-dicarboxylic esters having an aromatic group in the acid moiety attached at the 21 position. The reference specifically teaches the following compounds: 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-acetate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-propionate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-butyrate-21-benzoate; and 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-valerate-21-

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benzoate. (Col 4, lines 23-42) The reference also teaches that these compounds may be mixed with pharmaceutically acceptable excipients and applied topically to treat corticosteroid-responsive dermatoses. (Col 4, Ins 48-62)

The claims differ from the reference in that they include some compounds which contain differing halogens, methyl, etc. groups in the 6, 9, 11, and 16 positions. However, it is well known that compounds having a similar structure will have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-4-pregnen-3,20-diones having an optional double bond in the 1 and/or 9 positions or being substituted with similar groups in the 9, 11, and 16 positions. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any 17,21-dicarboxylic ester-4-pregnen-3,20-dione, including those of the instant claims, with the reasonable expectation that it would have the same use as the compounds of the reference, namely the treatment of dermatosis.

**B. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Kamano, et al.**

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Kamano, et al.

Kamano, et al teach 17,21-carboxylic esters and specifically teach the following compounds: 17-acetoxy-21-benzoyloxy-11-hydroxy-6-methyl-1,4-pregnadiene-3,20-dione and 21-benzoyloxy-11-hydroxy-6-methyl-17-propionyloxy-1,4-pregnadiene-3,20-dione. (Col 9) The reference also teaches that the compounds can be formulated into compositions useful for the treatment of dermal disorders. (Col 8, Ins 17-23 and 42-47)

The claims differ from the reference in that they include some compounds which have a halogen or methyl group at the 6, 9, or 16 positions and have

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additional substituents at the 11 position. However, it is well known that compounds having a similar structure will have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-1,4-pregnadien-3,20-diones. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any 17,21-dicarboxylic ester-4-pregnen-3,20-dione, including those of the instant claims, with the reasonable expectation that it would have the same use as the compounds of the reference, namely the treatment of dermal disorders.

**C. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Annen, et al. ('451).**

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Annen, et al. ('451).

Annen, et al. teach a 17,21-carboxylic ester-6,16-methyl-11-hydroxy-4-pregnen-3,20-dione optionally substituted in the 9-position and having an optional double bond in the 1-position. (See, Col 1, lns 15-42 of '451) The reference also teaches that the compounds can be used in pharmaceutical compositions for the treatment of various skin diseases. (Col 2, lns 10-29)

The claims differ from the reference in that they include some compounds which contain different groups in the 11 position. However, it is well known that compounds having a similar structure will have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-4-pregnen-6,16-methyl-3,20-diones having an optional double bond in the 1 position and having similar groups attached to the 9 position. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any 17,21-dicarboxylic ester-4-pregnen-6,16-methyl-3,20-dione, including those of the instant claims, with the reasonable expectation that it would

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have the same use as the compounds of the reference, namely the treatment of skin diseases.

Annen, et al. ('922 and '502) have not been applied in a rejection because they are cumulative the reference herein applied.

**D. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Page, et al.**

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Page, et al.

Page, et al. teach 17,21-dicarboxylic esters of 4-pregnen-3-20-dione having either an oxo or hydroxy group in the 11 position and having substituents similar to the instant claims in the 6, 9, and 16 positions. The compounds may also contain a double bond in the 1 position. (Col 1, lns 1-55) The reference also teaches the use of the compounds in pharmaceutical compositions for the treatment of corticosteroid-responsive dermatosis.

The claims differ from the reference in that they contain some additional compounds not taught by the reference, such as those having a 9(11) double bond. However, it is well known that compounds having a similar structure will have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-4-pregnen--3,20-diones having an optional double bond in the 1 position. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any 17,21-dicarboxylic ester-4-pregnen-6,16-methyl-3,20-dione, including those of the instant claims, with the reasonable expectation that it would have the same use as the compounds of the reference, namely the treatment of corticosteroid-responsive dermatosis.

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EP 072,200 is has not been applied because it is cumulative of the reference herein applied.

**E. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Annen, et al. ('763).**

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103 as being unpatentable over Annen, et al. ('763).

Annen, et al. teaches 17,21-dicarboxylic esters in which the 17 and 21 positions are substituted with an acyloxy group. (Col. 1, Ins 9-28) It also discloses the use of these compounds for the treatment of contact dermatitis. (Col 1, Ins 52-59) The instant claims differ from the reference by reciting specific species in which the 21 acyloxy is a phenoyloxy or a benzoyloxy and the 17 acyloxy is either a C<sub>1-8</sub>alkanoyloxy, a phenoyloxy, or a benzoyloxy. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species taught by the reference, including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of a genus would have similar properties and, thus, the same use as the genus as a whole.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly J. Kestler whose telephone number is (703) 308-4691. The examiner can normally be reached between 8 and 4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556. Any inquiry of a general nature or relating to

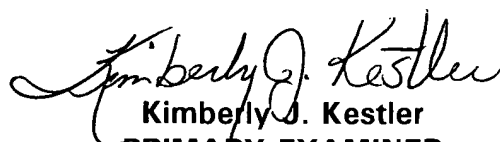


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the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
Kimberly J. Kestler  
PRIMARY EXAMINER  
ART UNIT 1204

KJK  
18 July 1995